

SOLICITATION FOR APPLICATIONS FOR A
COOPERATIVE AGREEMENT REGARDING
RISK ASSESSMENT MEETINGS, FORUMS, & RELATED EVENTS
COVERING SCIENTIFIC RISK ASSESSMENT AREAS
PERTINENT TO THE
U.S. EPA NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT

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NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT -
IMMEDIATE OFFICE
OFFICE OF RESEARCH AND DEVELOPMENT
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NCEA-I/O RESEARCH # NCEA-IO-98-01

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NCEA-I/O RESEARCH SOLICITATION

1.0 INTRODUCTION

The United States Environmental Protection Agency's (EPA) National Center for Environmental Assessment - Immediate Office of the Director (NCEA-I/O) operates under the Office of Research and Development (ORD). NCEA-I/O is issuing this "Request for Applications" (RFA) for Cooperative Agreements to obtain assistance to stimulate research in various scientific research areas by conducting workshops/forums on current risk assessment issues. The value of the cooperative agreement research awards represented in this document depends on future Congressional appropriations for EPA's research programs. The award is estimated to range from \$100,000 to \$300,000 total over a period of 3 years depending upon funding availability. Applications must be postmarked, dated by a delivery service or marked received by NCEA-W personnel by **August 21, 1998**. Applications will be thoroughly reviewed and evaluated by guidelines as set forth in this document. Interested parties are invited to submit a competitive Cooperative Agreement Application, including a full and detailed project application for funding consideration. The availability of this solicitation document was announced publicly on **June 22, 1998** in the Commerce Business Daily and the NCEA internet WEB site. The EPA reserves the right not to make any awards from this solicitation.

This document, sent to you in response to the national solicitation, provides information about NCEA-I/O's research mission, the research area for which applications are being solicited, the competitive process for awarding cooperative agreements, and the preparation of applications (see the Table of Contents on the pages preceding this section). We urge that you read and consider carefully the information presented in these sections before preparing an application.

2.0 BACKGROUND INFORMATION

NCEA-I/O, in partnership with the National Center for Environmental Assessment offices in Cincinnati, OH and Research Triangle Park, N.C., is a center for leadership in the evolution of human health and ecological risk assessment science and research by producing guidelines, procedures, and tools to support customers within the EPA and the environmental scientific community.

3.0 RESEARCH FOR WHICH APPLICATION IS BEING SOLICITED

3.1 Introduction

The National Center for Environmental Assessment (NCEA) wishes to provide assistance through a cooperative agreement to eligible organizations for the purpose of supporting a dialogue within the national and international scientific community in various fora (e.g., technical conferences, workshops, seminars, or colloquia) which will lead to an increased understanding of risk assessment issues thereby stimulating new research directions among scientific disciplines and

fostering interdisciplinary interest and cooperation. The NCEA is interested in funding up to three such forums annually over a period of three years. While the available funding is subject to the annual Congressional appropriation process and subject to the availability of annual funds, the NCEA anticipates support of up to \$100,000 annually.

The NCEA wishes to carry out a public purpose of support and stimulation as authorized by law for the activities in this request for applications. Therefore, the funds will not be available for award to scientific organizations of the Federal Government. The beneficiaries of the work will be the national and international scientific community.

3.2 The EPA Collaborative Role

The main role of EPA would be to provide scientific information on various risk assessment issues, as requested by the applicant. NCEA will be able to provide scientific information in many area's associated with health and ecological risk assessment. The multi disciplinary staff of NCEA has DVM, MD, and Ph.D level of health and/or ecological science expertise spanning many speciality areas: (e.g. toxicology, statistics, epidemiology, ecology, genetic toxicology, pharmacokinetics, etc.). We anticipate working with the applicant to ensure that meetings offer the proper balance of various environmental 'stakeholders' related to the specific issue at hand. EPA would also review the draft agenda of each specific meeting to ensure that the proper balance is represented at the meeting.

3.3 Project Description

The NCEA is seeking applications from well-qualified, eligible scientifically oriented organizations to propose a series of forums made up of experts of the best mix of scientists from the private and public sectors, academia, and the international community to foster scientific dialogue about risk assessment issues. The type of forum(s) is left to the applicant to propose. Forums may be of the conventional type including conferences, workshops, seminars or colloquia, or may be of a different, innovative type. The overall objective of these scientific interactions should be to identify the most current scientific issues and data gaps involving risk assessment and to identify the means of improving the practice of health and ecological risk assessment through research, education/communications, technology transfer or other means. The benefit to the greater scientific community will be to provide the most up-to-date information in the subject area and to identify specific approaches or other activities for improving the national and international risk assessment process, practice or procedure.

Improvements through research may be one of the outcomes of such forums under this project, but specific research proposals are not solicited or funded by this effort.

The funds available for this project will be awarded as a cooperative agreement. A cooperative agreement is different from a grant of funds in that the Government wishes to collaborate in the project. The science and policy of risk assessment include a variety of academic disciplines. The functional areas of risk assessment include hazard identification, dose-response

analysis, exposure assessment and risk characterization. Cross topic areas of uncertainty, risk extrapolation, pharmacokinetics, dose-response modeling and comparative risk are some of the many important sub-areas.

The proposal should describe up to three forums a year for up to three years. For each forum that is proposed, a full description of the forum type, the specifics of the forum, intended audience, the number planned for general attendance, number of planned impaneled experts, a description of the anticipated collaboration with the NCEA, along with a detailed budget. The topics of individual forums reflect the broad diversity of risk assessment or may be “chained” in logical progression of a number of forums, detailing a narrow risk assessment area leading to a fuller understanding.

The proposal for the first year activities should be detailed and precise. Subsequent years activities and budgets may be less precise and speak to general risk assessment themes planned for forums under consideration. This will allow the eventual recipient to consider and react to changing scientific issues and interest.

It is up to the proposer as to how the forums will be planned and conducted, but at minimum a forum should be interactive where ideas and opinions can be openly exchanged, discussed, and debated. The proceedings of the forum should be recorded and published.

For budget planning purposes, NCEA collaboration costs will be funded by NCEA. This includes administrative and travel expenses related to the collaboration.

4.0 FUNDING

4.1 Eligibility

NCEA-IO intends to establish a collaborative research relationship with a nonprofit research institution of higher education, individuals, or a nonprofit research organization with the primary purpose of supporting or stimulating ecological and human health risk assessment research. Applicants must be eligible to receive Federal Assistance under the Resource Conservation and Recovery Act (RCRA), the Solid Waste Disposal Act, the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), Toxic Substances Control Act or the Clean Air Act (CAA).

4.2 Award Value

While the value of the cooperative agreement research awards represented in this document depends on future Congressional appropriations for EPA's research programs, the awards are estimated to range from \$100,000 to \$300,000 total over a 3-year period depending upon funding availability.

4.3 Period of Performance

The U.S. EPA Award Official in the Grants Operations Branch is responsible for issuing the final award for the cooperative agreement. No costs should be incurred before the award agreement is issued. Funding to begin research under the cooperative agreement will not be available until after the award is made. Awards will be expected to begin in Federal FY-99 or FY-2000, with the start date to be determined by the Award Official. Assistance under this agreement will be provided for up to three years pending availability of resources.

5.0 ORD POLICY ON COOPERATIVE RESEARCH AND AWARD OF COMPETITIVE COOPERATIVE AGREEMENTS

5.1 Use of Cooperative Agreements

In preparing applications in response to this solicitation, applicants should consider the following relevant ORD policy with respect to the use of cooperative agreements. U.S. EPA funds extramural projects through both assistance and acquisition mechanisms (Memo from Christian Holmes dated December 2, 1992). By statute (31 USC 6305),

"An executive agency shall use a cooperative agreement as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when:

(1) the principal purpose of the relationship is to transfer a thing of value to the State, local government, or other recipient to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring (by purchase, lease or barter) property or services for the direct benefit or use of the United States Government; and

(2) substantial involvement is expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement."

Cooperative agreements may not be used as a mechanism to acquire goods or services for the direct benefit or use of the Federal government where a type of procurement contract is the appropriate instrument (31 U.S.C. 6303 (3)).

ORD is authorized under various statutes to conduct research and development in different areas of environmental science. It is ORD's policy that such research is appropriate for assistance agreements when the primary purpose of such research is to "carry out a public purpose of support or stimulation" as stated in 31 U.S.C. 6305.

Consequently, the research project areas described in this solicitation are distinguished by being primarily in support of U.S. EPA's broad research and development mission, and are

distinguished from other projects in the laboratory whose primary purpose is to deliver a required product for another U.S. EPA office. Products or services procured primarily for the direct benefit of another U.S. EPA office or for ORD scientists in conducting research and development, (e.g., analytical services, ADP support, and supplies) are inappropriate for acquisition through assistance agreements. Incidental development of products of use to ORD or a program office does not, in itself, preclude use of a cooperative agreement.

Cooperative agreements anticipate substantial involvement of U.S. EPA personnel in the activity contemplated by the agreement. This involvement may include:

- ! collaborative participation in the design, conduct, and interpretation of research activity;
- ! negotiated changes in direction of effort with the project;
- ! in-kind provision of services and/or equipment; and
- ! co-publication.

The specific type and extent of U.S. EPA involvement in the cooperative effort will be defined explicitly in the agreement.

While cooperative agreements are to include substantial involvement as described above, specific limitations are placed on the U.S. EPA's involvement.

- (a) Key Personnel - The professional qualifications/skills of key personnel (positions) should be designated in the cooperative agreement. The agreements shall state that U.S. EPA shall have the right of review and concurrence in the qualifications of personnel proposed to fill these positions. Becoming involved in the formal personnel processes of cooperating parties is inappropriate for U.S. EPA personnel.
- (b) Supervision of Cooperator Personnel - In order to sustain the collaborative relationship anticipated by the cooperative agreement and sustain effective cooperator management, U.S. EPA personnel shall not supervise or direct the day-to-day activities of cooperator personnel.
- (c) Contracting Under Cooperative Agreements - Use of contractors by cooperators is authorized; however, the role and cost of subcontracts must be clearly identified in advance in the cooperative agreement. The U.S. EPA personnel shall not be involved in selection or direction of subcontractors.
- (d) Project Officer Role - Within the scope of collaboration anticipated in the cooperative agreement, the U.S. EPA project officer is responsible for

assuring compliance with technical and management requirements, including peer review of publications, quality assurance procedures and documentation, key personnel and other special conditions, and periodic assessment of progress toward the stated objectives of the agreement.

5.2 Competition

It is ORD policy that, to the maximum degree feasible, opportunity to compete for the award of cooperative agreements will be afforded to all qualified scientific institutions or researchers. Solicitations are to be structured to provide both full and open opportunity for competition, and to ensure that a reasonable likelihood exists for applications to be submitted by more than one respondent.

Published solicitations for Applications for competitive cooperative agreements shall include discussion of the type and extent of U.S. EPA planned involvement in the assisted activity, the criteria to be employed in evaluating application and a discussion of the process for evaluation and decision. Decisions related to evaluation, ranking, and award of research cooperative agreements shall be fully documented, including criteria for evaluation, results of evaluation, and the basis for the award decision.

Applications submitted in response to a U.S. EPA competitive solicitation will not be considered if the proposer asserts a claim of confidentiality of information contained therein, unless explicitly allowed in this guidance.

The collaborative nature of the cooperative agreement process makes it appropriate for the project officer to negotiate the final form of the agreement with the principal investigator. However, to avoid giving an unfair competitive advantage to any applicant, it is important that the negotiation step not occur until all competitive applications have been reviewed and ranked and the decision official has made a tentative selection of the successful applications. Until that time, all Federal employees must avoid providing any information to any applicant that might confer an unfair competitive advantage. This does not preclude formal procedures for providing written comments back to applicants on applications or any other formal procedure that systematically treats all applicants equally.

The general U.S. EPA policy on peer review provides the framework for ORD specification of peer review requirements. Peer review of major competitive solicitations is desirable. Peer review of Applications for funding submitted in response to competitive solicitation is mandatory.

6.0 INFORMATION FOR INVESTIGATORS PREPARING APPLICATIONS

This section contains information of importance to research investigators preparing cooperative agreement full Applications. Information about the full application process and

application forms are found in the "Application Kit for Assistance." For an application, call Gladys Randolph 202-564-5305 or write to: EPA. Grants Operation Branch (3903R), 401 M Street, SW, Washington, DC 20460. Additional general information about legislation and regulations for assistance programs can be found in the Federal Register (Friday, September 30, 1982, Part VIII, pages 45056-45076) or in the Code of Federal Regulations (40 CFR 30). (Internet sites: www.whitehouse.gov/wh/eop/omb/grants/ and [WWW/epa.gov.odg/regs.htm](http://WWW.epa.gov.odg/regs.htm))

6.1 **Review Criteria**

6.1 Review Criteria

The following criteria (with the quantitative weight for each criterion given in parenthesis) will be used in the review of applications:

A. Qualifications (40)

1. Evidence that the applicant organization is highly recognized domestically and internationally for its efforts, past and present, to advance the science of human health and ecological risk assessment, both practical applications and the development of risk assessment methods (10).
2. Demonstrated ability to attract scientists of the highest repute to address risk assessment topics, including representatives from all stakeholder groups including academia, industry and non-government organizations, along with the ability to work in collaboration with U.S. government agencies to further the public interest (10).
3. Demonstrated expertise, scientific qualifications, time availability and organizational structure of the principal investigator and key personnel to support the proposed research (10).
4. Past ability to execute financial agreements (cooperative, grant and/or contract) with the U.S. government to the benefit of the public (10).

B. Administrative Capability (25)

1. Ability of the applicant to provide technical support, facilities, and equipment relevant to the successful completion of the research (10).
2. Ability to collate, format and arrange means to publish or otherwise disseminate the results of the activities contemplated under this assistance agreement to the scientific community and public (10).
3. Evidence of quality control/quality assurance mechanisms for implementing

and tracking the administrative components of the research (5).

C. Proposal Quality (35)

1. The extent to which the applicant demonstrates an understanding of the state of science in the proposed research on risk assessment and risk assessment methods, and the contribution of the applicant's proposed approach to advancing the state of the science (10).
2. The scientific merit of the proposed approach to answering research questions posed in the research, including the soundness of fundamental scientific and technical approaches, consideration of unique or innovative approaches evident in the application, and its proposed methods for gaining wide stakeholder participation and consensus (15).
3. The overall quality and clarity of the application regarding its objectives, proposed methods, ability to achieve these goals, and related funding information (10).

6.2 **Submission of Full Applications**

One original and five copies of each full application must be submitted. Completed applications that respond to this solicitation must be mailed by regular, priority, or express U.S. Mail or delivered by other delivery service, and received at the following address on or before the deadline indicated in the assistance package:

Regular Mail Service

David Kelley
U.S. Environmental Protection Agency
NCEA (MS-8623D)
401 M St. SW
Washington, DC 20460
Kelley.Dave@epa.gov (Internet)

Delivery Service address

USEPA/NCEA (8623D)
808 17th Street, NW
4th Floor, Suite 400
Washington, DC 20074

Applications that are postmarked, dated, or marked received after the deadline will not be considered.

6.2.1 **General Application Description**

The project narrative section of the application must not exceed thirty-five 8 1/2 x 11-inch, consecutively numbered pages of standard type (10-12) characters per inch), including tables, graphs, and figures. For purposes of this limitation, the "project narrative section" of the application must include all of the following items:

- (1) Description of Project
- (2) Objectives
- (3) Results or Benefits Expected
- (4) Research Support and Stimulation
- (5) General Project Information
- (6) Collaboration with NCEA Staff
- (7) Relevance to Research
- (8) Quality Assurance Narrative

Items 1,2,3, and 5 are described in the Application/Information Kit. For this specific solicitation, items 4, 6, and 7 must be included in the project narrative section. Since the primary purpose of this assistance is to "carry out a public purpose of support or stimulation," please address specifically under item 4 how this assistance will support and stimulate societal environmental research programs and accomplish a public purpose.

Proposers will observe Review Criteria in Section 6.1 with the assistance package and should prepare the application in such a way as to ensure that reviewers will be able to address the review criteria. Each application must also include an item (8) Quality Assurance Narrative Statement as described in Section 6.4.3. Another 5 pages may be used for this section.

Attachments, appendices, and reference lists for the narrative section may be attached, but are included in the 35-page limitation. Additional items not included in the 35-page limitation are the SF-424 and other forms; budgets; resumés; the abstract; and the cover sheet. The cover sheet must contain the following information:

- 1) Title of the application
- 2) Name of the institution or individual
- 3) Mailing address for disposition of the application
- 4) Name, phone, fax and e-mail information for the principal investigator

Resumés for each principal investigator should focus on education, positions held, relevant experience and accomplishments, and most recent or related publications. Itemized budgets, including justifications, must not exceed five consecutively numbered pages (excluding budget information on SF-424.) Applications not meeting these requirements will not be evaluated.

All Applications received by the due date will be date-stamped and reviewed to ensure that all forms and documents have been appropriately prepared. Correspondence will be mailed to each applicant submitting a application confirming receipt of the application. Incorrectly prepared forms and inadequate documentation can be grounds for rejection of the application from the evaluation process, and from subsequent consideration for funding.

6.2.2 Substantial Involvement of EPA Scientists in Cooperative Agreements

Section 3.2 of this document emphasizes the importance of collaboration in cooperative agreements. The fundamental role of collaboration with U.S. EPA scientists in the research activity contemplated by the agreement makes the cooperative research mechanism a distinctly different one from a grant mechanism, in which no collaboration is permitted. Examples of substantial

involvement with U.S. EPA scientists include: (1) collaboration in the design, measurement, analysis, and interpretation of the research activity; (2) collaboration in publishing articles or reports about the research; (3) collaboration in negotiating changes in direction of work under the specific agreement.

6.2.3 Quality Assurance Requirements

As indicated in U.S. EPA General Regulations for Assistance Programs (40 CFR 30.503), all applicants seeking financial assistance from U.S. EPA must submit with their application one of the following pieces of quality assurance (QA) documentation: Quality Assurance Narrative Statement, Quality Assurance Program Plan or Quality Assurance Project Plan. As part of the application that responds to this solicitation, each applicant must prepare a modified Quality Assurance Narrative Statement. This QA Narrative must discuss each of the quality elements listed below in the context of the research being proposed and any laboratory managing and performing analysis for the proposed research.

Additional information about the quality elements can be found in the American National Standards Institute document entitled, "Quality Management and Quality System Elements -- Guidelines" (ANSI/ASQC Q94-1987). The quality elements of interest with respect to this solicitation are:

1. Quality Management
 - ! Quality Policy
 - ! Quality Objectives
 - ! Responsibilities and Authority
2. Structure of Quality Systems
 - ! Quality Organizational Structure
 - ! Resources and Personnel
 - ! Operational Procedures
 - ! Quality Manual
 - ! Record keeping Policy
 - ! Measurement and Test Equipment Controls
 - ! Review and Evaluation of Quality Systems

U.S. EPA General Regulations for Assistance Programs (40 CFR 30.503) require successful applicants to develop and implement a Quality Assurance Program which is acceptable to the award official to receive a U.S. EPA Assistance Award. The quality Assurance Narrative Statement must be approved by U.S. EPA prior to award as being adequate to ensure that the organization is capable of preparing an acceptable Quality Assurance Project Plan (QAPP). While QAPP is not required as part of the application to be submitted for this competition, a QAPP must be prepared by those research organizations with Applications selected for awards and submitted to the EPA Project Officer for approval within 30 days after award, and before initiating data collection activities.

6.3 Review of Full Applications

NCEA-I/O seeks to balance scientific merit, relevance to risk assessment areas and opportunity for collaboration with EPA scientists in awarding cooperative agreements under this solicitation. The review and award process attempts to strike a balance between these three objectives, as well as ensuring fairness, flexibility, and accountability in the authorization of government expenditures.

The Review Panel (RP) for the applications will be composed of approximately two EPA scientists and one non-EPA scientist selected for their expertise in the research area. The most important criteria for award will be scientific merit and relevance to the advancement of exposure assessment science. (See Section 6.1 for description of criteria and weights.) The panelists will be required to certify that no conflict of interest is created through the individuals' participation in the panel or review process, and that the individual will not benefit, personally or financially, either directly or indirectly, from any aspect of participation in the review process. Panel members will not be permitted to discuss or retain applications after the completion of the review process.

The reviewers will provide both a numerical score and a written evaluation of the application. The TEP, then, will discuss and compare all final Applications, including considerations of the review criteria, all reviewers' comments, funding availability, and NCEA-W scientific staff expertise and time commitments. The TEP will prepare a written report of this process and make final recommendations as to acceptability for funding.

6.4 Selection of Applications by Decision Official

After RP recommendations are finalized in report form, the applications will be submitted to the designated Federal decision-making official for final funding decisions. For each application, the RP will provide the reviewers' written evaluations and scores. The decision official will select the most meritorious application or applications, based on the RP recommendations. This will not necessarily result in the highest-scored application receiving an award because of possible duplication and differences among the scoring criteria and among reviewers. The decision official also will provide written documentation explaining the final decisions.

After the selection process concludes, its tracking number, together with its written and numerical evaluations will be retained in a file by NCEA-IO. Names of panel members will not be available and will not be in the information included in the file. At this point also, a letter will be sent to each applicant that submitted a application that indicates whether the application is being considered for funding.

6.5 Negotiating a Final Cooperative Agreement

Following selection of applications for funding, negotiations will begin to develop a final cooperative agreement package. At this point, competition is concluded and all restrictions on

discussions with NCEA personnel are removed. Final issues to be negotiated include the selection of a U.S. EPA collaborator as project officer, final budgets and terms of the agreement, response to reviewer's comments, final arrangement for Quality Assurance including submission of a Quality Assurance Project Plan (QAPP) and other conditions. The purpose of the final negotiation step is to implement the Applications that are selected in the competitive process described above. Care will be taken to avoid making changes to the cooperative agreement that might have significantly affected the outcome of the formal review process, or the evaluation of the application by the TEP.

6.6 Award Process

The U.S. EPA Award Official in the Grants Operations Branch is responsible for issuing the final award for the cooperative agreement. No costs should be incurred before the award agreement is issued. Funding to begin research under the cooperative agreement will not be available until after the award is made. Awards will be expected to begin in Federal FY-98 or FY-99, with the start date to be determined by the Award Official.

6.7 Project and Budget Periods

Generally, ORD limits cooperative agreements to a project period of three years. Normally, funding is provided each year for a one-year budget period. However, no more than two year's funding may be provided at any one time. The recipient must submit continuation Applications for each additional funding period (budget period). The application should provide a budget for each year.

6.8 Other Information to Applicants

6.8.1 Peer Review of Publications

EPA regulations (40 CFR 30.518) encourage publication of the results of cooperative research agreements. Reports and informational material prepared under the cooperative agreement must be submitted to NCEA for peer review prior to publication. Cooperating authors must give consideration to any peer review comments from this review. If NCEA does not approve publication clearance for the reports or other material, then the cooperating party may publish the work, providing the publication includes the appropriate disclaimer statement. This requirement for peer review extends to publications based on research conducted during the period of performance, even if the publication is prepared after the completion of the performance period.

In contrast to reports and informational material, journal articles which are prepared under the cooperative agreement without collaboration and co-authorship of NCEA scientists may be submitted directly for publication to a refereed journal at any time. In this instance, the researcher must submit one copy of the article to the NCEA project officer when it is transmitted to the journal, and three copies of the article after it is published. Conversely, journal articles prepared with NCEA scientists as lead authors or coauthors must be submitted to NCEA for peer review and clearance

prior to submission to a journal.

6.8.2 Communication with EPA Employees During Competition

During the period of competition for cooperative agreements, it is illegal for any Federal employee to knowingly provide, or for a potential competitor to solicit, information about a cooperative agreement that could confer an unfair competitive advantage to the recipient of such information. To reduce both the potential for inadvertent communication of such information, and the appearance of conferring unfair advantage, it is ORD policy to restrict any communication about cooperative agreements undergoing competition to systematic communication that insures that all competitors have equal access to information. In furtherance of this policy, do not contact or engage in discussions with NCEA employees for the purpose of seeking clarification or additional information about the research areas being competed in this solicitation.